NEOORTHO

**510(k) Summary**

MAY 1 4 2014

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| **Proprietary Name** | NEOPLATE Spine Anterior Fixation System |
| **510(K) Number** | K132653 |
| **Date Prepared** | May 12, 2014 |
| **Submitter** | NEOORTHO Produtos Ortopedicos S/A<br>Rua Angelo Domingos Durigan 607,<br>Cascatinha<br>Curitiba-PR, Brazil 82020-340<br><br>Telephone: +55 41 3535-1033<br>Fax: +55 41 3535-1018 |
| **Official Contact** | Tara Conrad<br>TechLink International Consulting<br>18851 NE 29th Avenue Suite 720<br>Aventura, FL 33180<br>TEL– (305) 377-0077 |
| **Common Name** | Appliance, fixation, spinal Intervertebral body |
| **Trade Name** | NEOPLATE Spine Anterior Fixation System |
| **Regulatory Class** | Class II |
| **Product Code** | KWQ |
| **Classification Panel** | Orthopedic |
| **Regulation Numbers** | 21 CFR § 888.3060 |
| **Predicate Device** | K030327 Zephir Anterior Cervical System by Medtronic Sofamor Danek |

**Device Description**

The NeoOrtho NEOPLATE Spine Anterior Fixation System consists of a variety of shapes and sizes of bone plates, screws and instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

**Indications for Use Statement**

The NeoOrtho NEOPLATE Spine Anterior Fixation System is intended for anterior interbody screw/plate fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma, (including fractures), 3) tumors, 4) deformity (defined by kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

Note: this device system is intended for anterior cervical intervertebral body fusions only.

Warning: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

**Material**

The NEOPLATE is manufactured from titanium alloy as described in ASTM F136.

**Performance Data**

Mechanical testing was performed according to ASTM F1717. The specific tests performed were:

- Compression Testing
- Fatigue Testing
- Static Torsional Testing

The mechanical testing results demonstrate substantial equivalence to other legally marketed devices.

**Technological Characteristics**

The NEOPLATE System possesses the same technological characteristics as the predicate device. These include:

- Performance (described above)
- Basic design (plate and screw system)
- Material (titanium alloy)
- Size (dimensions are within the ranges of the predicate)

Therefore the fundamental scientific technology of the NEOPLATE System is the same as the previously cleared device.

**Conclusion**

The subject device and predicate device share the same indications for use, primary implant design and equivalent material of manufacture. In conclusion, the information provided and performance testing conducted demonstrate that the subject device is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

NEOORTHO Produtos Orthopedicos S/A
% TechLink International Consulting
Ms. Tara Conrad
Regulatory Affairs Manager
18851 Northeast 29th Avenue, Suite 720
Aventura, Florida 33180

Re: K132653
Trade/Device Name: NEOPLATE Spine Anterior Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 4, 2014
Received: April 11, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K132653

Device Name
NEOPLATE Spine Anterior Fixation System

Indications for Use *(Describe)*
The NeoOrtho NEOPLATE Spine Anterior Fixation System is intended for anterior interbody screw/plate fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma, (including fractures), 3) tumors, 4)deformity (defined by kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions. Note: this device system is intended for anterior cervical intervertebral body fusions only.

Warning: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ronald P. Jean -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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